

REMARKS

Claims 1-41, 54-61, 63, 68, and 74 were before the Examiner for consideration in this application. In this office action, Claims 1-4, 20, 23-39, 54-61, 63 and 74 are rejected under § 103(a) as unpatentable over Eldridge (U.S. 6,120,539 in view of Shaw (U.S. 5,879,366). Claims 5-19, 21, 22 and 40-41 are rejected under § 103(a) as unpatentable over Eldridge (U.S. 6,120,539) in view of Shaw (U.S. 5,879,366) in further view of Notaras (WO 9603091). For the reasons discussed below, Applicant respectfully traverses these rejections.

In this paper, Claims 1, 36, 54, 61 and 74 have been amended, no claims have been added, and previously withdrawn claims 43-53, 69-73 and 75-80 have been canceled. Accordingly, Claims 1-41, 54-61, 63, 68, and 74 remain before the Examiner for consideration. No new matter has been added with this amendment.

A. Claim Amendments

In this Amendment, Claims 1, 36, 54, 61 and 74 have been amended to further define the subject matter for which protection is sought and to expedite issuance of a patent. The Applicant respectfully submits that the claims as previously pending are patentably distinguished over the cited references or any combination thereof. However, to expedite prosecution, Applicant has amended the claims in order to clarify the features of Applicant's claimed invention. Applicant reserves the right to pursue the previously unamended claims or claims of broader scope at a later date.

B. §103(a) Rejection of Claims

1. The Examiner's Obviousness Rejections Are Deficient

The Examination Guidelines for Determining Obviousness Under 35 U.S.C. § 103 in View of the Supreme Court Decision in *KSR International Co. v. Teleflex Inc.* ("Examination Guidelines"), which were published in the Federal Register Vol. 72, No. 195 (Docket PTO-P-2007-0031) on October 10, 2007, apply the Supreme Court's decision in *KSR Int'l. v. Teleflex, Inc.*, 127 S. Ct. 1727 (2007) with regard to the issue of obviousness under 35 U.S.C. § 103(a) in relation to prior art. Applicant submits that the outstanding Office Action fails to satisfy the Examiner's burden in establishing an obviousness rejection.

Under the Examination Guidelines, and as reiterated by the Supreme Court in *KSR*, the framework for the objective analysis for determining obviousness under 35 U.S.C. § 103 is stated

in *Graham v. John Deere Co.* Obviousness is a question of law based on underlying factual inquiries. The factual inquiries enunciated by the Court are as follows:

- (1) Determining the scope and content of the prior art;
- (2) Ascertaining the differences between the claimed invention and the prior art; and
- (3) Resolving the level of ordinary skill in the pertinent art.

The Examination Guidelines confirms the role of Patent Office personnel as fact finders:

When making an obviousness rejection, Office personnel must therefore ensure that the written record includes findings of fact concerning the state of the art and the teachings of the references applied. In certain circumstances, it may also be important to include explicit findings as to how a person of ordinary skill would have understood prior art teachings, or what a person of ordinary skill would have known or could have done. Factual findings made by Office personnel are the necessary underpinnings to establish obviousness.

72 Fed. Reg. 57527 (Oct. 10, 2007).

The Examination Guidelines further provide that “Once the Graham factual inquiries are resolved, Office personnel must determine whether the claimed invention would have been obvious to one of ordinary skill in the art.” *Id.* “[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *Id.* at 57528-57529 (internal citations omitted). Under the Examination Guidelines, a rejection must offer specific support for the following rationales Examiners may use to show obviousness:

- (A) Combining prior art elements according to known methods to yield predictable results;
- (B) Simple substitution of one known element for another to obtain predictable results;
- (C) Use of known technique to improve similar devices (methods, or products) in the same way;
- (D) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results;
- (E) “Obvious to try”—choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;
- (F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations would have been predictable to one of ordinary skill in the art;

- (G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

Id. at 57529.

The pending Office Action fails to set forth the level of ordinary skill in the pertinent art, or who qualifies as one of ordinary skill in the field. Applicant submits that without such a finding, the Examiner's combinations are improper, as the Examiner has not established that the references proposed by the combinations would be known to one of ordinary skill in the art, nor that one of ordinary skill would have the requisite knowledge and ability to make the desired combinations.

Moreover, the Examiner has failed to provide explicit explanations supporting the obviousness rejections. The Examiner summarily concludes that "It would have been obvious to combine the features of the structure of Shaw that has multiple ePTFE membranes with a wire support with structure of Eldridge that teaches a support mesh with a single ePTFE membrane motivated to produce a biocompatible laminate for use in tissue repair that has the desired properties of porosity and resistance to tissue adhesion." Office Action at page 3. However, a person skilled in the art would not be motivated to combine Eldridge with Shaw "to produce a biocompatible laminate for use in tissue repair that has the desired properties of porosity and resistance to tissue adhesion." The Examiner fails to identify: (1) the knowledge one skilled in the art would possess, (2) what modifications the skilled person would need to make to combine the prior art references, and (3) whether that skilled person would have a reasonable expectation of success. Accordingly, Applicant submits that the Examiner's obviousness rejections are improper. More specific details relating to these missing inquiries and missing articulated findings are discussed in more detail below, along with Applicant's reasoned statements explaining why Applicant's claims are nonobvious over the cited art.

2. The Eldridge and Shaw References Cannot Be Properly Combined

a. The Eldridge Reference

Eldridge discloses a submicron porous sheet of expanded PTFE (ePTFE) (16) that is bonded to a first layer of MARLEX mesh (14), where the MARLEX mesh (14) adjacent to the ePTFE (16) is heated and pressurized to melt in order to fuse to the ePTFE (16). A second layer

of MARLEX mesh (12) is woven into or tacked together with the first layer of MARLEX mesh (14) to prevent the second layer from melting or fusing when the first layer of MARLEX is melted to adhere to the ePTFE (16), thus retaining the second MARLEX layer's tissue in-growth capabilities. Eldridge col. 1, lines 59-63 and 66-67, col. 2, lines 8-14.

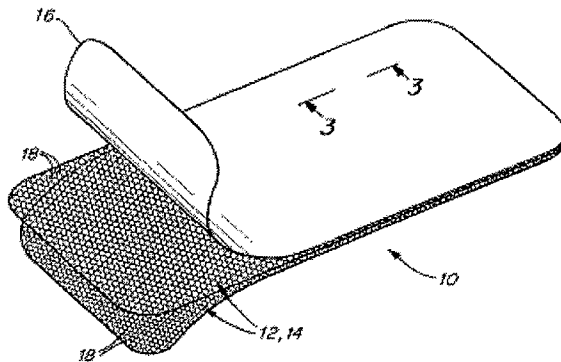


Fig. 1

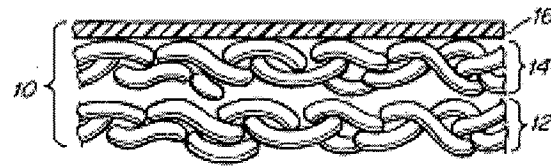


Fig. 3

The Office Action characterizes the adhesion resistant barrier layer of ePTFE (16) in Eldridge as a porous first membrane layer, and characterizes the MARLEX mesh (12, 14) in Eldridge as an open mesh bonding layer. Office Action pages 2-3. The Office Action admits that Eldridge does not teach a second porous membrane layer. Office Action page 3.

b. The Shaw Reference

Shaw discloses multiple layers of ePTFE film that are stacked and laminated to each other with no intermediary structures at Col. 5, lines 6-15:

“From 1 to about 200 plies (layers) of ePTFE film are stacked up and laminated to one another to obtain a membrane with the desired mechanical and structural properties. An even number of layers are preferably stacked together (e.g., 2, 4, 6, 8, 10, etc.), with approximately 2 to 20 layers being desirable. Cross-lamination occurs by placing superimposed sheets on one another such that the film drawing direction, or stretching direction, of each sheet is angularly offset by angles between 0 degrees and 180 degrees from adjacent layers or plies.”

c. The Combination of the Eldridge and Shaw References

Eldridge teaches a laminated film having an outer layer of porous and tissue infiltratable material and another outer layer comprised of an adhesion resistant microporous barrier (Eldridge col. 1, lines 44-48). Eldridge closes a defect by applying the repair fabric to just one side of the defect, and teaches retention of the repair fabric against the defect by means of tissue ingrowth

into the porous and tissue infiltratable material (Eldridge col. 2, lines 15-29; col. 6, lines 24-29 and col. 6, lines 37-39).

In Eldridge, the barrier layer (which may be ePTFE) discourages tissue ingrowth and viscera adhesion (col. 3, line 40 to col. 4, line 1). Eldridge does not use its ePTFE barrier layer on both sides of its repair fabric because to do so would defeat the function of the Eldridge device. Eldridge must have tissue ingrowth into the tissue facing side of the Eldridge repair fabric to stabilize the Eldridge repair fabric against the tissue defect.

Shaw also uses ePTFE in the Shaw device. Like Eldridge, Shaw does not teach tissue ingrowth into Shaw's ePTFE material. The design of Shaw's defect closure device does not require its device to be stabilized by tissue ingrowth. Shaw's device seals a defect by positioning a membrane on both sides of the defect, the device membranes being centrally joined and the device joint passing through the defect (Shaw, Figs. 7A – 7C, 5). The Shaw device is therefore mechanically retained in the defect without tissue ingrowth.

One of skill in the art would not be motivated to modify Eldridge's repair patch to use two or more layers of ePTFE as taught by Shaw because the ePTFE material taught by Shaw does not provide for tissue ingrowth into the material. As such, to combine the references in such a way would eliminate a critical aspect of the Eldridge repair patch.

Furthermore, as described in the quote from Shaw Col. 5, lines 6-15 above, Shaw prefers having its ePTFE layers directly laminated with other ePTFE layers for strength considerations. This direct ePTFE to ePTFE cross-lamination is not compatible with having a non-adhesive barrier in between ePTFE layers as the Office Action's Eldridge-Shaw combination proposes. In fact, putting a nonadhesive layer in between Shaw's ePTFE layers would also defeat the express purpose of having multiple layers laminated directly to each other for strength as emphasized in Shaw.

Thus, for at least the above cited reasons, it is improper to combine Eldridge with Shaw, and the Applicant respectfully requests the withdrawal of the rejections citing Eldridge in view of Shaw. All pending rejections rely on this improper combination of Eldridge with Shaw, so Applicant respectfully requests the withdrawal of the rejections of Claims 1-4, 20, 23-39, 54-61, 63 and 74 as unpatentable over Eldridge in view of Shaw (U.S. 5,879,366). Claims 5-19, 21, 22 and 40-41 are rejected under § 103(a) as unpatentable over Eldridge in view of Shaw in further

view of Notaras (WO 9603091). The addition of the Notaras reference does not cure the defects in the combination of Eldridge with Shaw, thus Applicant respectfully requests the withdrawal of the rejections to Claims 5-19, 21, 22 and 40-41.

3. Regarding Claim 54

Claim 54 recites, in part, “wherein the composite membrane has a composite membrane open surface area in the range between about 10% and about 50%.” The Office Action rejection of Claim 54 at pages 5-6 states that “Eldridge in view of Shaw differ from the current application and does not teach the property of open surface area in the range between about 10-50%.” The Office Action goes on to assert that “it is presumed that the property of open surface area would be inherent in this structure.” However, “the fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic.” M.P.E.P. § 2112(IV) (citing *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (emphasis added). “Inherency ... may not be established by probabilities or possibilities [and] the mere fact that a certain thing may result from a given set of circumstances is not sufficient.” *Id.* (citing *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950–51 (Fed. Cir. 1999) (emphasis added).

Furthermore, Claim 54 is not obvious in light of the cited Eldridge and Shaw references because as the Applicant’s specification states, “The term ‘composite membrane open surface area’ includes the term’s ordinary meaning, and also refers to the open surface area of the composite membrane barrier 15. As described above, the composite membrane barrier 15 has two sides, defined by first and second layers 250, 252. The composite membrane open surface area is the percentage of the compos[it]e membrane’s area that is open to both sides.” Specification at [0109] as published. Eldridge’s ePTFE layer is “an adhesion resistant, microporous barrier sheet for isolating the first sheet from sensitive tissue and organs after implantation.” Eldridge col. 1, lines 47-49. Eldridge discloses that the pores of ePTFE are scaled on the submicron level for:

“limiting the incidence of postoperative adhesions arising from the repair of an opening in a tissue or muscle wall. The method includes the steps of providing a composite prosthesis including first and second sheets of tissue infiltratable fabric and an adhesion resistant barrier sheet that is fused to the first fabric sheet, and then positioning the composite prosthesis with the second tissue infiltratable fabric sheet filling or covering, thereby occluding, the tissue or muscle wall

opening and with the barrier sheet facing away from the tissue or muscle wall opening and extending between a region of potential postoperative adhesion and the porous fabric sheets.”

Eldridge col. 1, line 67 and col. 2, lines 16-29. Applicant’s specification goes on to state that “The composite membrane barrier 15 generally allows cellular growth through and across the surface of the membrane barrier 15 within about two weeks after implantation, with endothelialization generally occurring within about one month.” Specification at [0110]. Thus, the cited references do not teach “wherein the composite membrane has a composite membrane open surface area in the range between about 10% and about 50%” either literally or inherently, and in fact teach away from open surface area in the range claimed as the references use ePTFE to prevent tissue in-growth in their disclosures.

Accordingly, for at least the reasons discussed above, Claim 54 distinguishes over the asserted reference combinations. Claims 55-60 depend from Claim 54 and recite additional novel and nonobvious limitations thereon. Accordingly, Claims 55-60 distinguish over the applied art for at least the reasons discussed above with respect Claim 54.

4. Regarding Claim 61

Claim 61 recites, in part, “wherein the composite membrane has a composite membrane open surface area in the range between about 10% and about 50%.” The Office Action rejected Claim 61 under 35 U.S.C. §103(a) as unpatentable over Eldridge in view of Shaw. The Office Action makes no statement with respect to any claims of inherency with respect to Claim 61. Nevertheless, for at least the reasons discussed above with respect to Claim 54, Claim 61 also distinguishes over the applied art. The Office Action states that “Eldridge differs from the current application and does not teach a frame or a laminate for a stent.” Office Action at pages 6-7. However, as discussed above, Eldridge and Shaw can not properly be combined because the combination would frustrate the purpose of each of the references. Claim 63 depends from Claim 61 and recites additional novel and nonobvious limitations thereon. Accordingly, Claim 63 distinguishes over the applied art for at least the reasons discussed above with respect to Claim 61. Claim 68, which also depends from Claim 61, stands with no rejections in the pending Office Action.

5. Regarding Claim 74

Amended Claim 74 recites, in part, “wherein the stent is generally cylindrical and is adjustable from a first configuration having a reduced diameter to a second configuration having an expanded diameter, the stent forming a conduit in the second configuration.” The Office Action at pages 6-7 states that:

Eldridge differs from the current application and does not teach a frame or a laminate for a stent. Shaw teaches a composite laminate that is configured with an elastic wire frame structure so that the device can be collapsed and then expanded. Shaw teaches a star shaped wire frame for a defect closure device as shown in Fig. 1 (col. 5, lines 28-40).

Eldridge and Shaw, alone or in combination, do not disclose or suggest a “stent is generally cylindrical and is adjustable from a first configuration having a reduced diameter to a second configuration having an expanded diameter, the stent forming a conduit in the second configuration.” For at least the reasons discussed above, Claim 74 distinguishes over the applied art, as well.

C. Conclusion

In light of the above comments, Applicant respectfully submits that all of the pending claims are allowable over the cited art. Applicant therefore requests that the Examiner issue a Notice of Allowability at the Examiner’s earliest convenience.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

Application No.: 10/802,395
Filing Date: March 17, 2004

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: 1-19-09

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